UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,960	02/25/2002	Jonathan B. Rothbard	019801-000240US	8395

20350 7590 03/15/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,960	ROTHBARD ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-36* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20021003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Sequence Listing filed May 31, 2005 is approved.

2. The drawings are objected to because in Figure 4, the second set of brackets in the second reactant and in the reaction product embrace an amidated amino acid repeating unit rather than an amino acid repeating unit. It is believed that the second end bracket in each structure should instead be placed between the carbonyl and the NH group. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The disclosure is objected to because of the following informalities: At page 10, line 17, "basement" is misspelled. At page 11, line 11, end quotation marks are missing after "Delivery enhancement". At page 13, line 9, it may be that "peptide" (second occurrence) should instead be "subunit". At page 28, line 22, "chloroacetic" is misspelled. At page 28, line 26,

"chloroacetate" is misspelled. At page 61, line 14, "bt" should be changed to "by". At page 61, line 30, "affect" should be changed to "effect". Appropriate correction is required.

4. Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the biologically active compound" at claim 10, lines 9-10, and claim 16, lines 6-7. The compound is not previously required to be biologically active. There is no antecedent basis in the claims for the phrase "the linking moiety" at claim 10, lines 10 and 12, and claim 16, lines 7 and 9. Independent claim 1 uses the terminology "linker". Claim 10 is indefinite because it is incomplete. There is no definition of the variables R^7 and R^8, which are used at line 16. Claim 12 is indefinite because it states that Y can be N, making it unclear as to what is attached to the third valence of the nitrogen atom.

5. Claims 8, 10-13, 16-18, 33, 34, and 36 are objected to because of the following informalities: At claim 8, line 1, "a" (second occurrence) should be changed to "at". At claim 10, line 2, "or" should be changed to "and". At claim 10, line 17, and claim 16, line 14, "R_6" should be changed to "R^6". At claim 11, line 3, and claim 17, line 3, a comma should be inserted after "phosphonate". At claim 18, line 1, "R_4" should be changed to "R^4". At claim 33, line 4, Applicants are requested to check the spelling of "psudotumor". At claim 34, line 3, "dilate" and "anesthetic" are misspelled. At claim 34, line 7, the second comma occurring after "anticholinesterase agents" should be deleted. At claim 36, line 1, "across" is misspelled. Appropriate correction is required.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-7, 9, 10, and 14-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-33, 40-58, and 88 of U.S. Patent No. 6,669,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '951 patent clearly anticipate instant claims 1-4, 6, 7, 9, 10, and 14-35. With respect to instant claims 5 and 36, because the same conjugate is delivered to the same animal ocular tissue according to the same method steps (e.g., via eye drops), inherently the conjugate will be delivered into and across the retina and will be transported across the blood-brain barrier in the claimed method of the '951 patent to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the claimed methods of the '951 patent and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of the '951 patent.

8. Claims 1, 4, 7, 9, 10, 13-16, 18, 22, and 24-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,593,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '292 patent anticipate claims 1. Note that the '292 patent claims the use of the same delivery-enhancing transporters (see, e.g., claims 15-17) as are claimed by Applicants, and claims administration to epithelial tissue of the eye (see claim 26).

9. Claims 1-7 and 9-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-61 of copending Application No. 10/740,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '365 application clearly anticipate instant claims 1-4, 7, 9, 10, and 14-35. With respect to instant claims 5, 6, and 36, because the same conjugate is delivered to the same animal ocular tissue according to the same method steps (e.g., via eye drops), inherently the conjugate will be delivered into and across the retina and optic nerve and will be transported across the blood-brain barrier in the claimed method of the '951 patent to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the claimed methods of the '951 patent and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of the '951 patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 8 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach or suggest administering a conjugate to ocular tissue where the conjugate comprises a compound attached to a delivery-enhancing transporter through a linker having the properties recited in claim 8. Note that in Applicants' parent application (now U.S. Patent No. 6,669,951) where linker properties are discussed (see, e.g., column 19, lines 39-54), the linkers are described as being cleaved at pH 7 rather than stable as is recited in instant claim 8.

11. The reference crossed off of the Information Disclosure Statement filed October 3, 2002 is a duplicate citation.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel
March 9, 2006